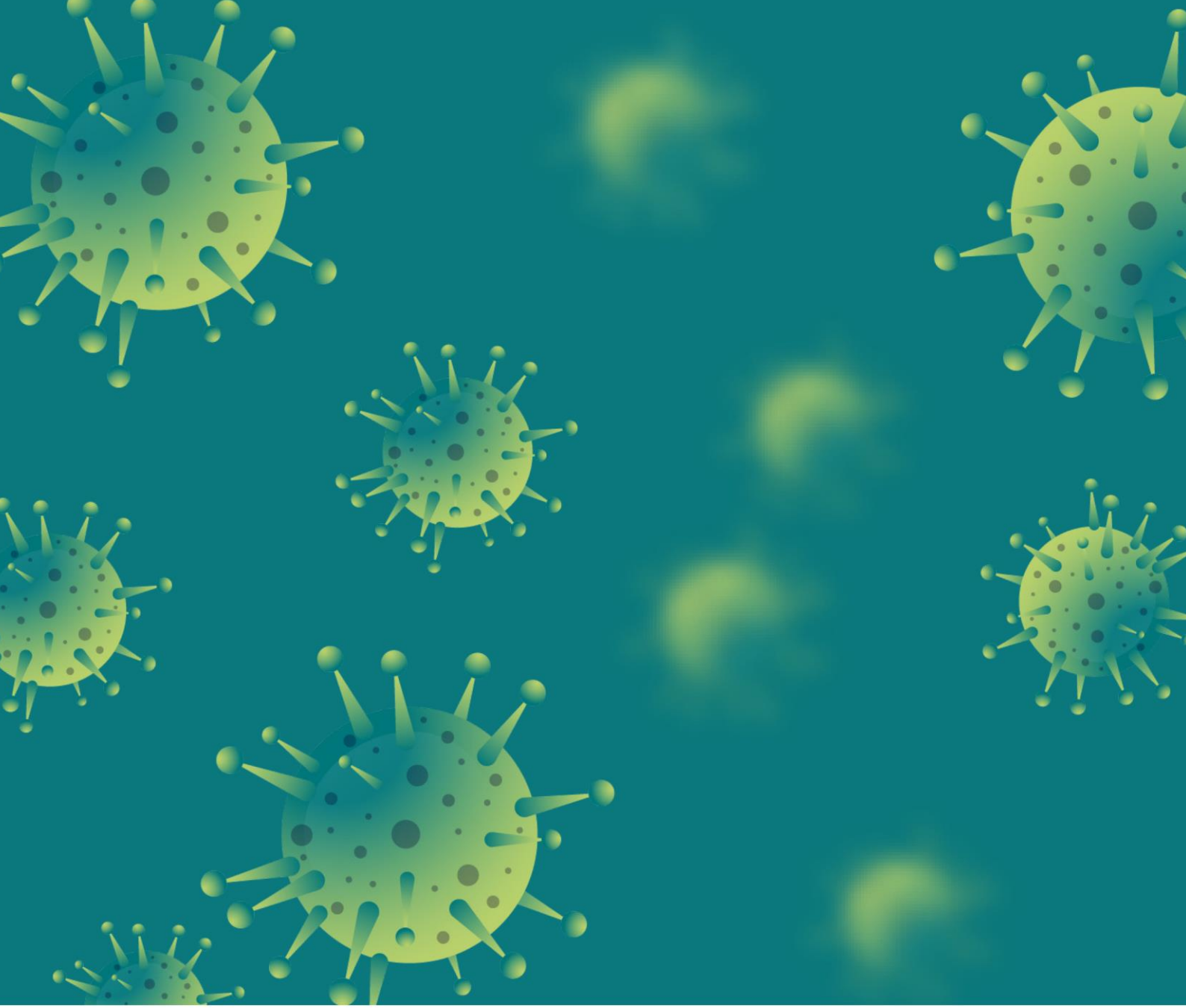

ACIPC

Australasian College
for Infection Prevention and Control

ACIPC Position Statement

Single-use devices

ACIPC
Australasian College
for Infection Prevention and Control

ACIPC guidelines for single-use device

Executive Summary

This position statement provides direction for use of single-use devices.

Recommendations

- Medical devices labelled as single use are not for reuse.
- Medical devices labelled as single patient use are reprocessed in accordance with the manufacturer's instructions before being reused on the same patient, and they must have TGA approval and be included in the ARTG.

Introduction

Single-use or single-patient use items, are items designed for single use and must not be used for multiple patients[1].

The responsibility of designating a medical device as single use or single patient use lies with the manufacturer and this must be clearly stated on the medical device or in the instructions for use. The Therapeutic Goods Administration (TGA) considers the reprocessing and/or reuse of a single use medical device to be a remanufacture of the device and therefore the original manufacturer is no longer responsible for the performance and safety of the device. Manufacture of medical devices, including remanufacture of single use devices, is regulated by the Therapeutic Goods Administration.

Items are listed as single use devices due to:

- Materials used in the medical device may not withstand the cleaning, disinfection or sterilisation process
- Difficulties in the cleaning, disinfection, or sterilisation of the device due to the design, e.g., narrow lumens [2]
- Reuse may compromise the functionality of the device and affect the safety, performance and effectiveness of the medical device and increase risk to the patient [3]

Reprocessing single use devices can lead to:

- Transmission of infection
- Device failure and/or degradation resulting in patient injury
- Issues with biocompatibility of the medical device
- Endotoxin reactions that cannot be removed by cleaning

Definitions

- **ARTG:** Australian Register of Therapeutic Goods is a public database of therapeutic goods that can be legally supplied in Australia.
- **Single use:** Equipment that is designed to be used on a single occasion for one patient and then discarded. Labelled with this symbol[1]: 
- **Single patient use:** Equipment to be used for one patient only. Single patient use equipment should not be used on more than one patient (i.e. it remains for exclusive use for one patient only). [1]. These items must be cleaned, disinfected or if able reprocessed and reused for designated patient only and in accordance with the manufacturer's instructions.
- **Reusable medical device:** A medical device intended for use by the manufacturer as suitable for reprocessing and reuse on multiple patients [4]
- **Medical devices**: Are defined as follows by the Therapeutic Goods Act 1989 [5]:
    - Any instrument, apparatus, appliance, software, implant, reagent, material or other article that is
        - Intended to be used by human beings in a range of uses related to disease, injury, disability, anatomy, contraception, and in vitro examination of a specimen derived from the human body for a specific medical purpose and
        - Does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means
    - The TGA require a healthcare facility that reprocesses single-use devices to be licensed as a manufacturer. A healthcare facility that reprocesses single use devices would be considered to be a manufacturer under the Act and thus would be required to conform to the regulation and be subject to audit to ensure compliance [5].

Literature Review

The reuse of single use devices exposes the patient to considerable risks, including infection and malfunction, that outweigh the perceived economic or environmental benefits of re-using a medical device [3].

A medical device that is intended for re-use must be validated by the manufacturer with the intention for the device to perform as expected on the first and subsequent uses, even after reprocessing. Reusable medical devices undergo extensive testing, validation and documentation to ensure performance will be maintained with reuse [3]. Items designed for single use have not undergone these reprocessing validation studies, and it is unknown how they will perform with reprocessing and repeated use [3]. Items labelled for reuse are required to have detailed manufacturers instructions outlining the requirements of cleaning and decontamination, disinfection and/or sterilisation, and certification from the TGA [6].

A single-use medical device that has passed its expiry date, or has been opened and unused shall only be reprocessed if it is permitted to in accordance with the devices manufacturer's instructions for reprocessing, and is performed in accordance with these instructions [4]. Medical devices that are labelled as intended for single use, and have been used shall not be reprocessed or reused [4].

When choosing single use or reusable devices, consideration should be given to [2]:

- The safety of the device, including
    - The risk of infection and contamination
    - if the device can be appropriately cleaned, disinfected and/or sterilized by the organization using the device
- The manufacturers safety data and instructions for use and/or reprocessing
- TGA approval
- Environmental impact including reprocessing, waste and disposal requirements
- Quality and performance of the device
- Cost-benefit analysis, including maintenance costs, and time and resources associated with reprocessing requirements
- Consideration given to environmental sustainability and recycling

Recommendations

Medical devices that are labelled as single use must not be reused, and medical devices that are labelled as single patient use are reprocessed in accordance with the manufacturer's instructions, before being reused on the same patient.

The reprocessing of single use devices must not be undertaken in a health service facility unless the facility is licensed as a manufacturer under the Therapeutic Goods Act (1989) and fully complies with the requirements and regulations of the act.

Health service organisations should continue to work with industry representatives to promote sustainability in healthcare and identify ways of safely reducing waste from impacting on our environment.

References

1. National Health and Medical Research Council, *Australian Guidelines for the Prevention and Control of Infection in Healthcare* 2019, National Health and Medical Research Council,: Canberra.
2. The Royal Australian College of General Practitioners, *Infection Prevention and Control Guidelines*. 2023, RACGP: Melbourne.
3. Regulating Medicines and Medical Devices, *Single-use medical devices: inplications and consequences of reuse*, M.h.p.R. Agency, Editor. 2021, MHRA: UK.
4. Standards Australia & Standards New Zealand, *Reprocessing of reusable medical devices and other devices in health and non-health related facilities (AS5369:2023)*. 2023, ASTM.
5. Therapeutic Goods Administration, *Therapeutic Goods Act 1989 Amendment Bill 2020*, P.o. Australia, Editor. 2020, Australian Government: Canberra.
6. Therapeutic Goods Administration. *Medical device labelling obligations*. Guidance and resources 2020 16 April 2020 [cited 2024 9 February]; Available from: https://www.tga.gov.au/resources/resource/guidance/medical-device-labelling-obligations.

Version

Version	Date	Addition/Amendments	Author	Review By
1.0	June 2012	New position statement	E. Gillespie, Chair Policy Committee	Executive Council
2.0	Sept 2015	Amended template, updated legislation & evidence	F. Wilson, ACIPC Policy Committee Member	Policy Committee ACIPC Executive Board
3.0	Oct 2016	Minor edits	T. van de Mortel, ACIPT Policy Chair	ACIPC Board of Directors
4.0	Feb 2024	Review and update	K. McKenna, ACIPC IPC CNC	Practice Guidance Committee ACIPC Board of Directors